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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,475	06/04/2001	Christos J. Petropoulos	2793/65166/JPW/JML/CMR	5338

7590 09/23/2003

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EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 09/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/874,475

Applicant(s)

PETROPOULOS ET AL.

Examiner

Ulrike Winkler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

The Amendment filed July 28, 2003 (Paper No. 15) in response to the Office Action of January 28, 2003 is acknowledged and has been entered. Claims 1-37 have been cancelled. Claims 38-88 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Applicants have provided a new Oath/Declaration (Paper No. 17). However, the signature of Neil Parkin is missing, this was one of the signature that had non-initialed changes made in the original Oath/Declaration. Correction is required.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 13, is attached to the instant Office Action.

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Drawings

The office acknowledges the correction to the drawing, the drawings have been approved by the draftsman.

Claim Rejections - 35 USC § 112

The rejection of claims 29 and 30 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **withdrawn** in view of Applicant's cancellation of the claims.

The rejection of claims 29 and 30 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is **withdrawn** in view of Applicant's cancellation of the claims.

Claim Rejections - 35 USC § 103

The rejection of claims 1-28 and 31-33 under 35 U.S.C. 103(a) as being unpatentable over Gao et al. (Journal of Virology, 1996), Petropoulos et al. (Antimicrobial Agents and Chemotherapy, April 2000) in view of Grovit-Ferbas et al. (Journal of Virology, 1998) and Trkola et al. (Journal of Virology, 1999) is **withdrawn** in view of Applicant's amendments to the claims.

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New rejection in view of applicant's amendment:

Claims 38-71 and 73-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are now amended to read that the viral construct comprises the patient derived envelope protein and nucleic acid. In order for a nucleic acid to be incorporated into the viral particle, the nucleic acid must contain a *cis*-acting psi packaging signal (see Luciw P., in Fields Virology, 1996, page 1927 column 2, last paragraph). A review of the specification (see the description for figure 2, on page 5) does not indicate that the patient derived viral envelope construct comprises a *cis*-acting psi packaging signal, without the packing signal the nucleic acid will not be packaged into the viral particle. The prior claims indicated that the viral expression vector and the envelope construct were co-transfected into a cell and the viral particles were collected. These particles would contain the viral expression vector including the indicator and the envelope protein but not the envelope nucleic acid. Therefore, the claims are rejected because they contain new matter that was not disclosed in the application as filed.

Claims 38-71 and 73-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are now amended to read that the viral construct comprises the patient derived envelope protein and

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nucleic acid. In order for a nucleic acid to be incorporated into the viral particle, the nucleic acid must contain a *cis*-acting psi packaging signal (see Luciw P., in Fields Virology, 1996, page 1927 column 2, last paragraph). A review of the specification (see the description for figure 2, on page 5) does not indicate that the patient derived viral envelope construct comprises a *cis*-acting psi packaging signal, without the packing signal the nucleic acid will not be packaged into the viral particle. The prior claims indicated that the viral expression vector and the envelope construct were co-transfected into a cell and the viral particles were collected. These particles would contain the viral expression vector including the indicator and the envelope protein but not the envelope nucleic acid. Therefore, the specification has not provided an enabling disclosure that would allow the ordinary artisan to make and use Applicant's now claimed invention.

Applicants are advised that amending the claims to indicate the viral envelope nucleic acid molecule does not incorporate into the virion would necessitate the reinstatement of the prior art rejection made on claims 1-28 and 31-33.

Claim 72 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites the limitation "identifying a cell surface receptor", however, the claim does not set out a strategy to accomplishing the goal of "identifying". Therefore, it is not clear how the process is achieved providing the steps outlined in the claim. The claim requires contacting the cell with a viral particle that contains an indicator and measuring the amount of indicator produced in the cell, the correlation step on how to "identify" the cell surface receptor

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responsible for the incorporation into of the viral particle into the cell with the signal produced is not described. Therefore, the claim is indefinite because it is not clear how to achieve the goal of “identifying”.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 72 is rejected under 35 U.S.C. 102(b) as being anticipated by Petropoulos et al. (Antimicrobial Argents and Chemotherapy, April, 2000).

The instant invention is drawn to a method of “identifying” cell surface receptors, the methods comprises the steps of contacting a cell which expressed cell surface receptor with a viral particle that comprises viral nucleic acid and indicator molecule, followed by measuring the amount of detectable indicator signal in cell that becomes infected by virus.

Petropoulos et al. discloses a method in which a viral particle comprising an indicator nucleic acid infected 293 cells (target cell) in culture, and viral replication was monitored by measuring luciferase activity (see page 921, column 1, last paragraph). The presence of signal indicates that the viral particle is able to enter the cell using the cell surface receptors present on the cell. Because the “process of identifying” the cell surface receptor is not clear (see 35 U.S.C. 112, second paragraph above) the invention is still anticipated by Petropoulos et al. because the reference sets out those steps in the claim that are clear.

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

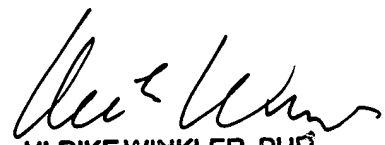
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


ULRIKE WINKLER, PH.D.
PATENT EXAMINER